

## 510(k) Summary

**SUBMITTER:** Covidien  
60 Middletown Avenue  
North Haven, CT 06473  
(203) 492-5299 (T)  
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**CONTACT PERSON:** Katherine Kassim  
Senior Specialist, Regulatory Affairs

**DATE PREPARED:** August 19, 2013

**TRADE/PROPRIETRY NAME:** Endo GIA™ Radial Reload with Tri-Staple™ Technology

**COMMON/USUAL NAME:** Surgical Stapler with Implantable Staples

**CLASSIFICATION NAME:** Staples, Implantable

**FDA PANEL NUMBER:** 79

**PRODUCT CODE:** GDW

**CLASS CODE:** Pursuant to 21 CFR 878.4750, an implantable staple is a Class II device.

**PREDICATE DEVICE(S):** Endo GIA™ Radial Reload with Tri-Staple™ Technology (K131705);  
Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology  
(K093410); Endo GIA™ Single Use Tan Reload with Tri-Staple™  
Technology (K101444)

**DEVICE DESCRIPTION:** The single use Endo GIA™ Radial Reload with Tri-Staple™ Technology places three radial (curved) staple rows 60mm in length on each side of a cut line and simultaneously divides the tissue between the third and fourth lines, creating a 60mm curved transection. The radial reload places height progressive titanium staple rows. The reloads may be inserted through an access device such as a hand access device or comparable access port. The Endo GIA™ Radial Reload with Tri-Staple™ Technology may be used with the Endo GIA™ Ultra Universal, Endo GIA™ Universal, GIA™ Universal and iDrive™ Ultra stapler handles.

**INTENDED USE:** The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

OCT 23 2013

TECHNICAL  
CHARACTERISTICS:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology black reload and tan reload are substantially equivalent and have not altered the fundamental scientific technology to the predicate devices with regards to stapling technologies. The following summary tables show the similarities and differences between the subject device and the predicate devices.

Substantial Equivalence Chart Black Reload	Endo GIA™ Radial Reload with Tri-Staple™ Technology Black Reload (subject devices)	Endo GIA™ Radial Reload with Tri-Staple™ Technology Purple Reload (predicate – K131705 )	Endo GIA™ Single Use Black Reload with Tri-Staple Technology (predicate – K093410)
Intended Use	The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open and minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substances, hepatic vasculature and biliary structures and for transection and resection of pancreas.	Same	The AutoSuture™ Endo GIA™ Staplers have application in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.
Staple Line Length	60mm	60mm	45mm or 60mm
Cartridge Color	Black	Purple	Same
Staple Sizes	4.0mm, 4.5mm, 5.0mm	3.0mm, 3.5mm, 4.0mm	Same
Cartridge Geometry	Curved	Same	Straight
Staple Rows	3 rows	Same	Same
Staple Material	Titanium	Same	Same
Single Use	Yes	Same	Same
Disposable	Yes	Same	Same
Sterilization	The subject devices shall be sterilized via a validated ethylene oxide (ETO) cycle to a SAL of 10 <sup>-6</sup>	Same	Same
Packaging	The subject devices shall be packaged in a sterile tray with Tyvek® lid. Each tray is packaged in a display box.	Same	Same

Substantial Equivalence Chart for Tan Reload	Endo GIA™ Radial Reload with Tri-Staple™ Technology Tan Reload (subject device)	Endo GIA™ Radial Reload with Tri-Staple™ Technology Purple Reload (predicate: K131705)	Endo GIA™ Single Use Tan Reload with Tri-Staple Technology (predicate: K101444)
Intended Use	The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open and minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substances, hepatic vasculature and biliary structures and for transection and resection of pancreas.	Same	The AutoSuture™ Endo GIA™ Staplers have application in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.
Staple Line Length	60mm	60mm	45mm or 60mm
Cartridge Color	Tan	Purple	Same
Staple Sizes	2.0mm, 2.5mm, 3.0mm	3.0mm, 3.5mm, 4.0mm	Same
Cartridge Geometry	Curved	Same	Straight
Staple Rows	3 rows	Same	Same
Staple Material	Titanium	Same	Same
Single Use	Yes	Same	Same
Disposable	Yes	Same	Same
Sterilization	The subject devices shall be sterilized via a validated ethylene oxide (ETO) cycle to a SAL of $10^{-6}$	Same	Same
Packaging	The subject devices shall be packaged in a sterile tray with Tyvek® lid. Each tray is packaged in a display box.	Same	Same

**MATERIALS:**

All components of the Endo GIA™ Radial Reload with Tri-Staple™ Technology are similar to the predicate Endo GIA™ Radial Reload with Tri-Staple™ Technology. All materials are similar and are in accordance with ISO Standard 10993-1.

**PERFORMANCE DATA:**

Design verification and pre-clinical validation studies were conducted to demonstrate that the proposed devices Endo GIA™ Radial Reload with Tri-Staple™ Technology black reload and tan reload are safe and effective and perform as intended. In vitro and in vivo testing to support the intended use of this device includes:

- In Vitro
  - Firing Force
  - Retraction Force
  - Staple Formation
- In Vivo
  - Free Bleed Evaluation
  - Air Leak Test
  - Burst Evaluation
  - Tissue Grasping and Trauma
- Biocompatibility

The result of these tests demonstrates that the proposed devices Endo GIA™ Radial Reload with Tri-Staple™ Technology black reload and tan reload are substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Covidien, LLC  
Ms. Katherine Kassim  
Senior Regulatory Affairs Specialist  
60 Middletown Avenue  
North Haven, Connecticut 06473

October 23, 2013

Re: K132493

Trade/Device Name: Endo GIA™ Radial Reload with Tri-Staple™ Technology  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: Class II  
Product Code: GDW  
Dated: September 23, 2013  
Received: September 24, 2013

Dear Ms. Kassim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K132493

Device Name: Endo GIA™ Radial Reload with Tri-Staple™ Technology

### Indications for Use:

The Endo GIA™ Radial Reload with Tri-Staple™ Technology has application in open or minimally invasive general abdominal, gynecologic, pediatric and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, i.e. low anterior resection. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

**David Krause -S**

\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical Devices  
510(k) Number: K132493